

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re the Application of: **Miyachi**

Application No. **10/784,145**

Filed: **February 23, 2004**

For: **Methods of Using Zonisamide as an Adjunctive Therapy for Partial Seizures**

Docket: 222443

Commissioner of Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**Information Disclosure Statement**

Pursuant to 37 CFR §§ 1.56, 1.97 and 1.98, Applicant brings to the attention of the Examiner the documents listed on the attached PTO-1449 Form. A copy of the PCT publication listed on Sheet 1 and all the references listed on Sheets 3-5 are submitted herewith.

Applicant also brings to the attention of the Examiner the following pending applications:

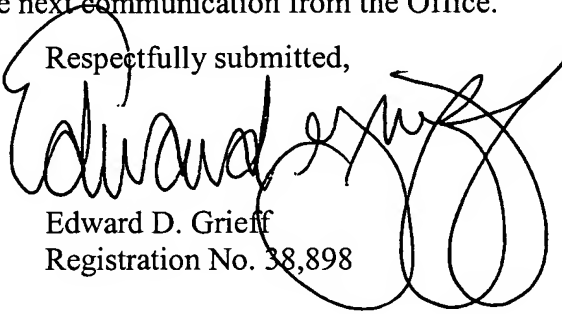
- (i) US 10/644,935 filed August 21, 2003;
- (ii) US 10/752,515 filed January 8, 2004;
- (iii) US 10/752,523 filed January 8, 2004;
- (iv) US 10/752,516 filed January 8, 2004;
- (v) US 10/752,522 filed January 8, 2004;
- (vi) US 10/753,955 filed January 9, 2004;
- (vii) US 10/753,956 filed January 9, 2004;
- (viii) US 10/753,958 filed January 9, 2004;
- (ix) US 10/784,145 filed February 23, 2004; and
- (x) US 10/753,957 filed January 9, 2004.

The submission of this Information Disclosure Statement does not represent that a search has been made and does not constitute an admission that the listed documents are material to patentability or that the listed documents are prior art.

The Information Disclosure Statement is being filed prior to the mailing date of a first office action on the merits and prior to a Notice of Allowance. Accordingly, no fee is due. The Commissioner is, however, authorized to charge any necessary fees or credit any overpayments to Deposit Account No. 22-0261 to maintain the pendency of the application.

Applicant respectfully requests that the Examiner initial and return a copy of the enclosed PTO-1449 Form with the next communication from the Office.

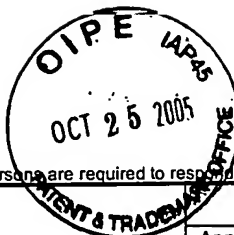
Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Edward D. Grieff', is written over the typed name and registration number.

Edward D. Grieff  
Registration No. 38,898

Date: October 26, 2005

VENABLE LLP  
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Phone: 202-344-4382



PTO/SB/08A (07-05)

Approved for use through 07/31/2006. OMB 0651-0031  
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Substitute for form 1449/PTO

Complete if Known

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

1

of

5

Application Number

10/784,145

Filing Date

2-23-04

First Named Inventor

Lieberburg

Art Unit

Examiner Name

Attorney Docket Number

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US- 4,172,896	10-30-1979	Uno et al	
		US- 6,342,515	1-29-2002	Masuda et al	
		US- 6,495,601	12-17-2002	Hochman	
		US- 2004/0029941	02-12-2004	Jennings	
		US- 2004/0142992	07-22-2004	Shellenberger	
		US- 2004/0198668	10-07-2004	Gadde et al	
		US- 2005/0137144	06-23-2005	Gadde et al	
		US- 2005/0143322	06-30-2005	Gadde et al	
		US- 2004/0033965	02-19-2004	Gadde et al	
		US- 2002/0143579	10-03-2002	Docherty et al	
		US- 2005/0043773	02-24-2005	Lieberburg	
		US- 2005/0043705	02-24-2005	Lieberburg	
		US- 2005/0043704	02-24-2005	Lieberburg	
		US- 2005/0154034	07-14-2005	Lieberburg	
		US- 2005/0154032	07-14-2005	Lieberburg	
		US- 2005/0154033	07-14-2005	Lieberburg	
		US- 2005/0154035	07-14-2005	Lieberburg	
		US- 2005/0154036	07-14-2005	Lieberburg	
		US- 2005/0154037	07-14-2005	Lieberburg	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
		WO 00/45817	08-10-2000	Raza et al		

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>		<b>Complete if Known</b>	
		Application Number	10/784,145
		Filing Date	2-23-04
		First Named Inventor	Lieberburg
		Art Unit	
		Examiner Name	
Sheet 3	of 5	Attorney Docket Number	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Faught et al, Neurology, 57:1774-1779 (2001).	
		Knudsen et al, Pediatric Neurology, 28(3):184-189 (2003).	
		Shimizu et al, Brain & Development, 19:366-368 (1997).	
		Asai et al, Internal Medicine, 41(2):138-141 (2002).	
		Matzner et al, Scand. J. Haematol., 21:309-312 (1978).	
		Aymard et al, Scand. J. Haematol., 26:330-332 (1981).	
		Lapes et al, Lancet, 1:198 (1976).	
		Selby et al, Cancer Research, 49:5736-5747 (1989).	
		Saltzstein et al, Cancer, 12(1):164-182 (1959).	
		Maeoka et al, Epilepsia, 38(5):611-613 (1997).	

Examiner Signature		Date Considered	
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		Schmidt, Epilepsy Research, 00:1-12 (2002).	
		LaRoche et al, JAMA, 291(5):605-614 (2004).	
		Sobieszek et al, Polish Journal of Pharmacology, 55:683-689 (2003).	
		Rodgers et al, American Journal of Surgery, 111:792-794.	
		Merkle et al, Eur. Radiol., 12:1979-1992 (2002).	
		Leppik, Epilepsia, 42(Suppl. 4):1-6 (2001).	
		Lazarou et al, JAMA, 279(15):1200-1205 (1998).	
		Kanoh et al, Jpn. J. Clin. Hematol., 37(3):239-243 (1996).	
		Gurwitz et al, The American Journal of Medicine, 109:87-94 (2000).	
		Fujimoto et al, Drug Res., 40(II), Nr. 8, 855-858 (1990).	

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		French, Epilepsia, 43(9):951-955 (2002).	
		Ellison et al, Journal of Surgical Research, 30:241-248 (1981).	
		Center for Drug Evaluation and Research, "Preventable Adverse Drug Reactions: A Focus on Drug Interactions," pp. 1-42 (2002) at <a href="http://www.fda.gov/cder/drug/drugReactions/default.htm">www.fda.gov/cder/drug/drugReactions/default.htm</a>	
		NDA 20-789/S-001: Zonegran (zonisamide) Capsules 25, 50, 100 mg; FDA Approved Labeling Text - August 22, 2003 (pages 1-21).	
		Zonegran (zonisamide) Package Insert, NDA 20-789, pages 1-12 (December 2004).	

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